CIRCULATORY SYSTEM DEVICES PANEL
AGENDA

October 9, 2014
Circulatory System Devices Panel
Classification Panel
Gaithersburg Hilton

On October 9, the committee will discuss and make recommendations regarding the classification of more-than-minimally manipulated allograft heart valves (MMM Allograft HVs). A MMM Allograft HV is a human valve or valved conduit that has been aseptically recovered from qualified donors, dissected free from the human heart, and then subjected to a manufacturing process(es) that alters the original relevant characteristics of the tissue (21 CFR 1271.3(f), 21 CFR 1271.10(a)(1), and 21 CFR 1271.20). The valve is then stored until needed by a recipient. An example of such a manufacturing process is one that intentionally removes the cells and cellular debris with the goal of reducing in vivo antigenicity.

8:00 a.m.	Call to Order Introduction of Committee	**Richard Page, MD** Chairperson
	Conflict of Interest Statement	**Jamie Mae Waterhouse, MBA** Designated Federal Officer
8:10 a.m.	Reclassification Presentation	
8:25 a.m.	Questions from Committee	
8:35 a.m.	FDA Presentation	
9:35 a.m.	Questions from Committee	
9:45 a.m.	Break	
9:55 a.m.	Industry Open Public Hearing	
10:25 a.m.	Questions to Industry OPH Speakers	
10:35 a.m.	General Open Public Hearing	
10:55 a.m.	Panel Deliberations	
11:20 a.m.	Break	
11:30 a.m.	FDA Questions to the Panel	
1:00 p.m.	Adjournment	

*** Open Public Hearing –** Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.